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A STUDY TOUR OF THE PHARMACEUTICAL INDUSTRY

IN THE

WEST BANK AND GAZA STRIP

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Report */

prepared by the
UNIDO Secretariat

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INTRODUCTION

Several attempts to begin drug production in the West Bank were made prior to 1967. However, each attempt faced difficulties either in obtaining a licence or in financing for any serious production start-up plans. At least one firm, Jordan Chemical Laboratory, was issued a licence but limited its production to creams, ointments and simple preparations.

The 1967 Israeli occupation of the West Bank came as a severe blow for the few drug stores and agents that imported all of their pharmaceuticals from abroad. Due to obstacles imposed by the occupation, stocks of drugs were depleted without any prospect of renewal by the Palestinian import agents or drug stores. The general feeling was that the West Bank would, sooner or later, become dependent on Israeli pharmaceutical firms and importers of foreign drugs.

As a result of this situation and of the vacuum created in drug supplies, a number of pharmacists and concerned citizens attempted to establish pharmaceutical production on the West Bank. Until recently, pharmaceutical production in Gaza had not been attempted.

The initiators of pharmaceutical production on the West Bank were initially hesitant to commit their monies to such a project, due both to the uncertain future of the West Bank

and to the difficult economic situation following the the 1967 Israeli occupation. However , by 1969 nine small pharmaceutical firms with limited production and facilities were in existence. The Israeli authorities were unhappy with this situation and cancelled the licences of the existing firms, subsequently issuing only two licences. This forced the existing companies to merge into two : Palestine Medical Company and the Jordan Chemical Laboratory. After further manipulations a third licence was issued to the Jerusalem Pharmaceutical Company.

Between 1970 and 1975 more licences were issued allowing the establishment of several new pharmaceutical firms on the West Bank. The reason for such a move was not clear, but changing Israeli attitudes towards the West Bank plus internal problems within the newly merged firms were contributing factors.

Currently there are seven pharmaceutical firms in the West Bank , six in the greater Ramallah/Al Bireh area and one in Beit Jala. In addition, there is a small pharmaceutical firm in Nablus which produces veterinary preparations. This firm was not included in our survey. Two pharmaceutical firms are presently being established in the Gaza Strip. It must be stressed that some of these companies produce cosmetics as part their production line and one that also produces insecticides packaged in aerosol cans.

PHARMACEUTICAL COMPANIES IN THE WEST BANK

The seven pharmaceutical companies in the West Bank with their year of establishment and capital are listed in Table 1. A total of 691 products is currently manufactured, as shown in the Table. These numbers were obtained from both interviews and the presciber`s guides. However, the prescriber`s guides for six of the companies were not current. In addition to pharmaceuticals, the figures include a small number of cosmetic preparations and aerosols manufactured by some of the companies. It is note-worthy that these numoers fluctuate, depending on : market needs, availability and cost of raw materials, economic benefit to the manufacturing company, and competition from other manufacturers. Several products also include the same active ingredient in different dosage forms and concentration.

Table 1. Description of the West Bank Pharmaceutical Companies.

Company	Year established	Capital Per J.D	Number of Products *
Jordan Chemical Lab.	1969	150.000	121
Palestine Medical Co.	1969	150.000	140
Jerusalem Pharmaceuticals ltd.	1969	300.000	81
Balsam Medical Co.	1970	300.000	94
Birzeit Pharmaceutical Co.	1974	350.00	110
Eastern Chemical Co.	1975	118.500	86
Gama Chemical Co.	1978	100.000	73

* Refer to text for details.

The number of pharmacists, chemists, and the overall number of employees is shown inTable 2. It can be concluded that the number of pharmacists and chemists employed represents about 12% of the total working force. We believe that this percentage remains constant. However, the total number of employees in each company is unstable and can vary from one month to the next.

Table 2. Number and Training of Employees.

Company	Pharmacists	Chemists	Total Number of Employees
Jordan	2	2	30
Palestine	3	3	45
Jerusalem	2	2	48
Balsam	2	3	35
Birzeit	2	4	44
Eastern	2	1	17
Gama	1	1	18

Space, Equipment and Raw Materials

The space which each company occupies and the area allocated to the various divisions is described in Table 3. The Jerusalem Pharmaceutical, Balsam Medical, Birzeit Pharmaceutical and the Jordan Chemical occupy their own buildings. The others operate in rented facilities. Eastern Chemical and Palestine Medical have had more than one building in close proximity to each other. Gama Chemical is currently constructing a facility of about 1,000 square meters. The companies do not base the number of products they manufactue on the size of the production area or, for that matter,for the total area of the company.

Table 3. Available Space in Square Meters.

Company	Production (%)	Control Lab (%)	Storage (%)	Offices (%)	Total*
Jordan	670 (42)	20 (1)	500(31)	400(25)	1600
Palestine	400 (40)	15 (2)	500(50)	100(10)	1000
Jerusalem	650 (30)	50 (2)	650(30)	250(11)	2200
Balsam	1150 (49)	50 (2)	500(21)	470(20)	2350
Birzeit	400 (25)	60 (4)	800(50)	150(9)	1600
Eastern	200 (36)	8 (2)	200(36)	100(18)	550
Gama	100 (29)	20 (6)	100(29)	35(10)	350

* Total includes hallways, corridors & others.

Areas devoted to production and storage clearly occupy most of the space. There is no correlation between the space devoted to production and the number of products manufactured. However, there is some positive correlation between the number of products manufactured and the percent area devoted to storage. Areas allocated to storage are not sufficient for company needs, as the companies complained to us about the shortage of storage and warehouse facilities.

The space assigned for the quality control laboratory is considered inadequate for analyzing the large number of drugs produced by any one company. Unfortunately, the quality control laboratory does not play as important a role as it should, due to many factors discussed later. Six of the seven West Bank companies provided us with the list of their equipment(Appendix A). Balsam Medical refused to provide us with a list of its equipment

and instrumentation. From our onsite visit Balsam's equipment and instrumentation for production and quality control appear to be similar to any of the other companies. The laboratory equipment at all companies meets the minimum requirements subscribed by the Jordanian law.

All equipment, spare parts and raw material are imported, in most cases, directly by the companies from foreign sources. Some packaging materials such as cardboard boxes, plastic containers and glassware is bought primarily from local West Bank sources. During our interview, we did not find any problem in acquiring any of the necessary materials. Also adequate spare parts are kept in stock. The companies depend on their own experienced employees to service and maintain their production equipment. Occasionally companies cooperate regarding machine maintenance. They do not rely on Israeli service personnel.

The companies have geared their production to take frequent power interruption into consideration. Some of them have their own generators and voltage stabilizers. Water supply seems to be adequate to meet their needs.

Productive Capacity and Related Problems

The output of the West Bank companies amounts to approximately

30% of their productive capacity. This low number is due to the limitation of having a small and highly competitive market, coupled with an inability to export either via Jordan or through Israeli ports.

Attempts to export West Bank pharmaceutical products through Jordan met many difficulties and is currently at a stand still. The Arab Boycott Organization requires the import of all raw materials needed for production via Jordan. This requirement presents many difficulties to the companies although they are willing to go through this procedure. At one point in the negotiations, the Jordanian Government approved the export of some products after proper registration. A number of companies registered some of their products; however, Jordan retracted its approval and stopped any drug registration procedures. Presently export to and through Jordan seems to be impossible. Export to other countries via Israeli ports is also difficult. The West Bank companies are limited in both their productive facilities and available capital. In addition, it is not possible to obtain a statement of origin with Jordan as the source. Since the products are not registered and marketed in Jordan, this cannot be done.

FINISHED PHARMACEUTICALS.

Description of Products

The number of pharmaceutical products currently manufactured bythe

seven West Bank firms exceeds six hundred. These products are marketed in different dosage forms and in different concentrations when appropriate. Table 4 shows the various dosage forms and the number of products in each form manufactured by the companies. It does not include any cosmetics, aerosols or detergents. The figures were obtained from our interviews and the prescriber's guide of each of the companies.

It has been difficult to obtain precise numbers since modifications in the kind and number of products can be introduced at any time. A decision for deletion or addition of certain products is made by the Board Of Directors on recommendation of doctors or sales agents, or is based on production cost, availability of raw materials, and competition from other products. However, the figures shown can be considered fairly accurate. All the companies manufacture a large number of products in the form of tablets, capsules and syrups or suspensions. Ampules are manufactured only by three companies, namely, Birzeit, Palestine and Jerusalem. Eastern can be considered to be the leader in the preparation of eye drops since it has recently acquired a small West Bank firm in existence since about 1970. It is obvious from the table that none of the companies specializes in a certain dosage form.

Table 4. Dosage Forms Manufactured by West Bank Companies.

Type	Company						
	Jordan	Palestine	Jerusalem	Birzeit	Balsam	Eastern	Gama
Tablets	39	34	24	31	29	11	6
Capsules	7	16	11	12	18	14	7
Suppositories	16	7	6	7	-	-	-
Ampules	-	18	6	22	-	-	-
Ointments & Creams	12	10	8	6	7	9	7
Syrups & Susps.	25	30	19	21	30	19	17
Eye, Ear & Nose drops.	8	14	-	2	3	19	-
Lotions	1	2	1	-	1	-	1
Granules	2	1	-	-	2	-	-
Powder	2	6	2	-	-	1	2
Mouth Wash.	-	1	1	-	1	1	1
Lozenges	-	2	-	-	1	-	-
Paint	2	-	-	-	1	2	1

Table 5 is an attempt to list the various types of products in each pharmacological class. The figures are derived from the prescriber's guide of each company. Six of these prescriber's guides are at least three years old and only Birzeit was able to provide us with 1983 guide. The other companies expect a new edition within a few months. The products mentioned in these guides are constantly being modified as mentioned earlier. All the products are included in the 30 different categories shown in Table 5. In some cases, a product can fit into more than one category. However, such products were entered only once and placed in the most suitable category. In addition, a product manufactured in more than one concentration has been entered only once.

An examination of Table 5 shows the overlap between the companies and any possible specialization that exists among them. These companies clearly have many products in common, especially in the classes of antibacterials, antiinflammatory-antirheumatic agents, antitussives, analgesics - antipyretics, vitamins -hematinics, and dermatological preparations. From our interviews, it has been concluded that the three best selling classes for any of the companies were the antibacterials, antiinflammatory - antirheumatic agents, and the analgesics - antipyretics.

Table 5. Number of Products in Each Pharmacological Class

Product	Company						
	Jordan	Palestine	Jerusalem	Birzeit	Balsam	Eastern	Gama
Analgesics Antipyretics	10	4	2	5	5	1	3
Chemotherapeutic Agents.	8	20	7	9	13	5	4
Antiinflammatory Antirheumatic.	10	8	4	3	7	1	-
Intestinal Antiseptics/Antidiarrheas	5	4	1	1	4	1	1
Antacids	3	2	1	-	2	1	1
Antihistaminics	4	2	1	2	1	1	-
Anthelmintics Antiamebics	1	2	2	1	3	1	1
Antispasmodics Anticholinergics	4	3	4	2	2	2	-
Antitussives Expectorants	5	5	1	2	4	3	1
Vitamins/hematinics	7	10	7	5	2	5	3
Muscle Relaxants	-	-	-	-	2	1	-
Tranquilizers/Sedative hypnotic	3	2	1	1	1	-	-
Antiasthmatics	7	2	1	1	1	1	-
Hypoglycemics	1	-	1	-	-	-	-
Urinary Antiseptics	2	1	-	-	1	-	-
CNS Stimulants	1	-	-	-	-	-	-
Laxatives	3	-	-	-	-	2	-
Diuretics	1	1	-	-	-	-	-

Table 5. Number of Products in Each Pharmacological Class (Cont.)

Product	Company						
	Jordan	Palestine	Jeruslem	Birzeit	Balsam	Eastern	Cama
Antiemetics	3	1	1	2	1	-	-
Peptic Ulcer Agents	-	1	1	1	-	-	-
Gargles/mouth paints	2	3	1	-	2	3	1
Ointments/Creams Powders	11	11	8	5	5	7	8
Eye,Ear, Nose drops	8	14	-	2	3	19	-
Aphrodisiacs	1	-	-	-	2	-	-
Antihemorrhoids	3	-	-	-	-	-	-
Hormones - Anabolic	-	-	-	6	-	-	-
Antihypertensives	-	2	-	2	-	-	-
Fertility Agents	-	1	-	1	-	-	-
Cardiotonic Agents	-	1	-	-	-	-	-
Oxytocic, Uterine bleeding	-	1	-	-	-	-	-

Table 5 also indicates that the manufacture of certain critical and highly potent drugs is not a top priority. This includes cardiovascular preparations such as antihypertensives, antianginal agents, antiarrythmics, antiatherosclerotics, digitalis, cerebral and peripheral vasodilators, antifibrinolytic agents and diuretics together with the hypoglycemic agents, hormones, contraceptives, and enzyme preparations. In fact, there are only two diuretics produced by two different companies, namely Jordan and Palestine, one cardiotonic by Birzeit, six hormonal preparations by Birzeit, two hypoglycemics by Jordan and Jerusalem. In addition, preparations for antiparkinsonism, muscle relaxants and antidepressants are not numerous. A large variety of dermatological preparations which contain antibacterials, antifungal agents, antihistaminics, and steroids in various combinations are produced and amount to about 57 preparations. There are about 46 different eye, ear and nose drop preparations.

From our discussions with the firms' executives, it was obvious that they are reluctant to introduce critical and potent products such as the cardiovascular preparations, partly because the companies do not want to commit themselves to such products, but most importantly, due to the hesitation observed among the doctors who are unwilling to experiment with a new but critical product on their patients.

Thus medical doctors depend mainly on foreign products first, followed by Israeli products second.

Efficacy and Quality

The information included in this section has been obtained mostly through interviews conducted with physicians, and other concerned individuals. The list of people interviewed is included in the acknowledgements section. In all cases, a list of questions was asked, followed by a general discussion in order to obtain an impartial and reasonable evaluation of the efficacy and quality of the various products. With the physicians, we have concentrated mostly on the product's efficacy and with pharmacists our concern was with the product's quality.

Efficacy is a difficult property to determine and needs long clinical investigations coupled with laboratory data. Information included in this section is based on interviews. Before reaching any conclusion with regard to efficacy, it is important to determine whether proper diagnoses have been made. Unfortunately, we cannot always guarantee proper diagnosis with all the doctors. In addition, a number of drugs, including antibiotics, are overly and unnecessarily prescribed without proper diagnosis. Many patients go to more

than one physician and do not come back to the same physician for a check-up. These and other factors make the determination of efficacy by the prescribing physician a difficult task. We believe that we were able to obtain reasonably accurate information from some of the physicians, who were following a scientific approach in the evaluation of the West Bank Pharmaceutical products.

We found that a general practice among a large number of doctors is to prescribe a foreign antibiotic in preference to an Israeli product for a seriously sick person. The West Bank Product is only prescribed in mild cases. Physicians in general have no confidence in the locally manufactured antibiotics and have complained about their efficacy. Many physicians insist that their lack of confidence is based on experience and experimentation. We also found little confidence in the bronchodilators, diuretics, hypoglycemics, and the antiinflammatory - antirheumatics. This does not mean that all such products were found to be inefficacious at all times. In fact, some doctors feel that there maybe variations from one batch to another. This discourages them from prescribing any such product for serious cases.

Other less critical products such as analgesics - antipyretics, antidiarrheal, and antacids are prescribed and doctors

had fewer complaints about their efficacy. There have been complaints about the efficacy of the dermatological preparations, suppositories and vaginal fungicidal inserts. The efficacy of the vitamin preparations is still questionable and thus physicians favor the foreign or Israeli products. The acidity of some of the ampules has also been found objectionable resulting in decreased efficacy and discomfort to the patient. Some of these problems were presented by concerned physicians to the companies and in some cases certain modification were introduced.

The conclusion we were able to draw is that the overall efficacy of some West Bank products is low. It is to be understood that a number of products are believed to be quite efficacious and are prescribed routinely. On the other hand, some of the physicians are unwilling to experiment with the patients and thus rely heavily on the foreign and Israeli products. We noticed that an additional contributing factors to the hesitation in use of the local product is the belief that such products are not regularly controlled, studied, evaluated and modified, as is the case with the foreign products.

With respect to quality, most individuals interviewed believe that significant improvements in the quality of the products have been introduced in the last two years. There

are still complaints with regards to tablets coating, hardness, friability , discoloration, caking of some suspensions, microbial growth, and leaking bottles. In addition, there are complaints about the slow disintegration of suppositories. The high glycerin content in some suppositories has been reported to result in diarrhea. The sterility of eye drops is questionable and precipitate formation occurs in some batches. Another problem is the reported nonuniformity in the color of capsules of certain products resulting in confusion of the patient and the pharmacist. In general, all problems have been significantly decreased over the last two years.

Since September 1982, the Israeli authorities have required an analysis of each batch of antibiotics. The authorities also run random spot checks and analyses of other local products on the market. This is carried out by one person who collects samples at random from the market and submits them to an Israeli analytical laboratory : The Institute for the Standardization and Control of Pharmaceuticals. This sampling is by no means exhaustive and does not cover every batch of a product on the market. The result of such analyses become available at least two to three weeks after sampling and in most cases longer. In the interim the drug would have reached the market. Recall procedures by the companies can take another month. This resultsin the consumption of

a fair amount of a drug before any recall notices take effect. The same applies to the antibiotics, since they can be marketed before receiving the results. Table 6 is a cumulative list of all products since September 1982 which did not meet the standards as determined by the Israeli analytical laboratory and which were required to be withdrawn. While none of the problems was critical or dangerous in nature, such data reflect on the quality and efficacy of these products.

Recently the Israeli authorities have also required inclusion of the manufacturing date and expiration date (if any) on each product, both on the container and outer packing. No product is to be sold five years after manufacturing, or three years, in the case of an antibiotic.

Shelf life and stability studies performed by the companies are in most cases, believed to be inadequate. By checking samples of products at doctors' offices, it has become evident that deterioration of some products occured with time. Such problems include discoloration, coating cracking, disintegration of some tablets, caking and microbial growth. It is not clear if the companies are aware of such problems or have had them documented. Stricter and more careful quality control of in-process material, final products, and shelf-

Table 6. List of Recalled Drugs.

JORDAN CHEMICAL LABORATORY

Product	Batch No.
1. Diasix Tab.	120
2. Paravomine Tab.	621
3. Diapect	388
4. Codinal Tab.	773
5. Codinal Tab.	777
6. Codinal Tab.	776
7. Rufen Tab.	106
8. Novodexon Elixir.	All Batches.
9. Neospasmyl Suppos.	1221
10. Ampitricine Caps.	126
11. Vomazine Drops.	227

PALESTINE MEDICAL CO.

1. Neopectal Susp.	8742
2. Urosept Caps.	8723
3. Oxycin Caps.	8781
4. Dopamine Tab.	8836
5. Deqasept Paint.	8270
6. Dologesic Caps.	8624
7. Nystagyl Vag. Tab.	8534

JERUSALEM PHARMACEUTICAL CO.

1. Urocycline P. Caps.	0128210
2. Olvit drops	All Batches.
3. Dexamin Tab.	0198210
4. Magnagel Susp.	7825

BIRZEIT CO.

1. Abcedin Tab.	4474
2. Becovit Amp.	4566
3. Neokal Tab.	4144
4. Decomb Cream.	4678

Table 6. List of Recalled Drugs.
(Cont.)

BALSAM MEDICAL & CHEMICAL CO.

Product	Batch No.
1. Balsprim Susp.	1920
2. Flu Syr.	1975
3. Ultragel Susp.	1986
4. Ibufen Tab.	1849
5. Terabal Caps.	1755
6. Protogyl Tab.	1191

EASTERN CHEMICAL CO.

1. Ampen Caps.	2138
2. Otocidine Ear drops	2152
3. Medocin Caps.	2053
4. Cefadin Caps.	2118
5. Ponsan Caps.	1049
6. Decongex Nose drops.	2157
7. Prodin Caps.	1069
8. Locasept N. Oint.	1003
9. Chloroceline Eye drops.	3056
10. Otocidine ear drops.	3176

GAMA CHEMICAL CO.

1. Solvocillin fort Caps.	1489
2. Policillin Susp.	1516
3. Amoxyl Caps. 500mg.	1532
4. Gamacycline Eye Oint.	1509
5. Clenzo mouth paint.	1023
6. Amoxyl Caps.	1496
7. Gamacycline skin Oint.	1638
8. Neutrolox Susp.	1652
9. Baby cure lotion.	1670
10. Zinc Oxide Oint.	1110
11. Icthyol Oint.	1639
12. Gamavit with Iron Syr.	1591
13. Aspiril C. Tab.	1366
14. Solvocillin fort Caps.	1653
15. Gamacycline Eye Oint.	1598
16. Amoxyl Caps. 250 mg.	1649
17. Amoxyl drops N.	1246
18. Neutralox Susp.	1713
19. Aspiril C. Tab.	1733
20. Amoxyl Caps. 500mg.	908
21. Clenzo Mouth paint(10cc)	875

life is needed to allow for modifications and to guarantee a better quality.

Physicians and pharmacists are disturbed by the wide variety of competing local products. Both groups expressed interest in better coordination and specialization among companies so as to decrease the number of competing products and conserve efforts and resources towards the production of a smaller number of highly efficacious products.

ESSENTIAL DRUGS NEEDED

The West Bank is a good market for Arab products, as well as competing Israeli and foreign products. Israeli pharmaceutical companies can produce drugs more cheaply than the West Bank firms. Moreover, the Israeli firms have a larger and more open market, are more aggressive in marketing and have the support of their government. Foreign products, on the other hand, enjoy a good international reputation. An adequate supply of all kinds and classes of drugs is provided through these three sources.

The Arab products, in most cases, are 10 to 20% cheaper than the Israeli products and 30 to 40% cheaper than the foreign products. However, some Arab products are more expensive

than the Israeli equivalents. The West Bank products account for 30-40% of the local market (depending on the area), Israeli products for about 40%, and foreign products for the rest. From our interviews, it seems the West Bank companies are reluctant to get into the production of critical and dangerous drugs, and also of less economically rewarding products. It is obvious from Table 5, that the classes of drugs missing from production include the cardiovascular preparations such as the antianginal, antiarrhythmics, antiatherosclertics, digitalis, and cerbral and peripheral vasodilators.

In addition, local firms manufacture only two antidiabetics, one diuretic, two antihypertensives, and one antidepressant. Another area which needs improvement is that of hormones, enzyme preparations, and the central nervous system agents. However, all of the above missing products are adequately supplied by Israeli and foreign companies at prices which the West Bank firms might not be able to meet. It is our opinion, that with proper specialization and consolidation of activities, the West Bank companies would be capable of producing some of the above-mentioned products at competitive prices. In addition, the companies would have to implement stricter product quality control measures. This would increase physician`s and consumer`s confidence in such needed products.

CONSOLIDATION OF ACTIVITIES

In 1969, nine small pharmaceutical firms in the West Bank produced a small number of pharmaceuticals to fulfil some local needs. In 1970, these companies were consolidated into three main companies, in order to meet the authorities licencing requirements and regulations. In the same year, however, more licences were issued and the number of companies increased to the seven currently existing.

In 1976 and 1977, The Physicians`Union attempted to assist the companies in their development, and with the consolidation of their activities in order to cut down on competition, improve product quality and decrease consumer cost. However this effort did not succeed despite more than ten meetings between the companies and the physicians.

The Pharmacists`Union has also made several attempts and is currently trying to consolidate the activities of the companies, including monitoring product quality and controlling prices. Very recently the Pharmacists`Union proposed the establishment of a technical committee whose members would include the head of the Physicians`Union, head of the Pharmacists`Union and head of the Dentists`Union, in addition to various Pharmacisits and Academicians.Such a commit-

tee has not yet been officially established and may not be accredited by the companies. However, we are not optimistic that such an effort will succeed. These efforts have been aimed at assisting the companies in their development, improving product quality, decreasing costs and reducing the heavy burden laid on pharmacists to carry a large number of similar products. Also pressure on physicians to prescribe products for the various companies is reduced.

From our interviews, it has been concluded that the top selling products are common to all of the companies and include antibiotics, analgesics - antipyretics, and anti-inflammatory - antirheumatics. Thus each company is reluctant to give up products that may reduce its profit margin. The competition among these companies takes various forms and includes offering bonuses to pharmacies, free samples, gifts to some doctors who may or may not be shareholders in the company, and discounts on various products. In addition, there is competition from Israeli and from foreign products. The Israeli companies specialize more among themselves, have a larger and open market and obtain support from their Government. Thus they provide tough competition.

As a result, there have been several meetings and discussions among the West Bank companies to consolidate

their activities. Proposals have included a reduction in the number of companies, specialization in certain pharmacological classes of drugs, specialization within the same class of drugs, and specialization in certain dosage forms. These proposals have not been fully approved or implemented. All such efforts have reached a dead end basically due to the self-interest of each company and its shareholders. Presently the only existing coordinating body among the companies is the Committee of The Arab Pharmaceutical firms in the West Bank city of Ramallah. This committee is limited in its functions and its efforts are mostly directed towards : 1) Challenging any unfavourable decisions taken by the occupying authorities, and 2) the coordination of local tenders.

Based on our interviews and the pharmacological classification of the various products (Table 5), it is obvious that some of the companies have attempted to manufacture unique products to avoid any competition. For instance, two diuretics are produced by only two companies, namely Jordan and Palestine, four antihypertensives by Birzeit and Palestine, two hypoglycemics by Jordan and Jerusalem, one antidepressant by Jordan, three muscle relaxants by Balsam and Eastern, and six sex hormones by Birzeit. Some micro-encapsulated raw material is imported and packaged by Balsam.

It has been, also, obvious to us that the competition among these companies is great. Most company executives are not optimistic about any unification, consolidation of activities or specialization. It seems that they are not presently facing any serious challenges that would force them to unify. However, we do see a great need for closer cooperation. The companies now have the basic equipment to manufacture various products with very minimal, if any, quality control. Any consolidation of activities would allow them to upgrade product quality, have better product control and should prove economically rewarding.

Thus we would like to recommend the following options or possibilities ranked in order of preference :

i) Reduction of the number of companies to two. This could be accomplished by unifying them on a sound scientific basis and merit, taking into consideration expertise, facilities and any currently existing specialization, but without consideration of any individual preferences or interests.

ii) Specialization among the existing companies based on drug classes. This could be done by subdividing the three best-selling classes of drugs, namely the antibiotics, analgesics - antipyretics, and antiinflammatory-antirheumatics. Each of the three classes would be manufactured

by two companies only. In addition, the companies could subdivide the remaining twenty seven classes of drugs mentioned in Table 5 among themselves.

iii) Specialization based on the various dosage forms. For instance, ampules are currently manufactured by Birzeit, Jerusalem and Palestine, while Eastern, Palestine and Jordan produce several types of eye drops. This kind of specialization could be evaluated, reorganized, and extended to cover all dosage forms and companies.

Any of the above possibilities could be a starting point for the reorganization of drug production in the West Bank. Such a reorganization is essential in order to decrease the competition among the Arab companies and thereby improving their position to compete with Israeli and foreign products. Such a move would revitalize the companies, as they have been adversely affected by the latest currency devaluation and economic slump on the West Bank. In fact, the latest devaluation has reduced the price gap between West Bank and Israeli products. In addition, such a move would allow each company to concentrate on a limited class of drugs which should result in better controlled and more marketable products. Pharmacists would be less pressured to carry a wide number of products and physicians would be under less pressure to prescribe products from different companies. This can better guarantee the health

and safety of the consumer.

GUIDELINES FOR IMPROVEMENT

The following guidelines have been prepared, based on interviews and on-site inspection of the facilities of each of the seven West Bank companies.

A. Buildings and Facilities.

The seven West Bank firms vary extensively in the size and organization of their facilities and also in the extent to which such facilities are maintained. Jerusalem, Birzeit, Balsam and Jordan occupy modern, reasonably spacious facilities constructed to serve the purpose of drug manufacturing. Eastern, Palestine and Gama operate from modified rented facilities which are not spacious enough to suit their needs. Adequate space in any drug manufacturing company is important in allowing for the orderly placement of equipment and material to prevent mixups. In addition, it facilitates adequate cleaning, maintainence and proper operation in the manufacturing, processing, packing, labeling or holding of drugs.

An important aspect of any facility is, also, the division within the plant of the various production processes (both

machines and products). This is important in order to reduce cross contamination and to prevent mixups. The manufacture and processing of the penicillins must be performed in separate areas having their own independent ventilation system in order to prevent cross contamination with other products.

Ventilation has been poor in some of the companies and noneexistant in others. Proper ventilation, including filters and prefilters with humidity control regulates the environment in the buildings and thus prevents contamination from external sources. Each filling machine must have a dustcollecter capable of removing not only powders but broken tablets and pieces. The dust collection system can be installed on the roof or near each machine. Areas producing aseptic compounds and areas for the dispensing of all raw material should have a laminar flow system.

The seven companies have substandard storage facilities. The storage areas are not clearly divided and defined to prevent contamination or mixups. On more than one occasion we have observed damp, moldy storage areas with raw materials lying around in a disorderly and unsanitary way.

The sanitation aspect of any company should include : Personal hygienic practices, prevention of infestation by

vermin, flies and other insects, cleaning schedule of equipment and utensils, and sanitary maintenance of toilets and washing facilities. Also included is the cleanliness of plant surroundings, and waste disposal. These aspects are loosely follow by the pharmaceutical companies. Thus we would like to recommend the following:-

1) Expansion of the current facilities is needed for Palestine, Eastern and Gama. Birzeit, Jordan and Jerusalem should introduce new sections for some of the production process and for storage. However, it should be stressed that before investing in such costly expansion, priority should be given to consolidation of activities and possible unification.

2) There should be clear divisions of the various production stages. Our recommendations are :

i) To have separate weighing rooms with their own air handling system.

ii) A typical granulating room should be subdivided into a milling and sizing booth, a blending booth, a mixing and a granulating booth and a drying area with drainage in each booth to facilitate cleaning.

iii) Tablet and capsule production should have separate rooms for tablet compressing and capsule filling, each equipped with humidity control devices. Each machine should have its own separate booth. Such rooms should have ample space to accommodate inprocess testing equipment such as a

tablet hardness tester and balances.

iv) A separate room should be assigned for tablet coating with proper noise insulation and dust control. Drainage should be provided for easy cleaning of the coating pans and floors.

v) Liquid manufacturing should be carried out in a special area with proper cleaning and sanitation facilities, particularly to avoid microbial contamination in some products. Routine microbiological and chemical testing must be performed on water and sterile liquids. It is necessary to have separate facilities for oral and external or cosmetic preparations.

vi) Ointments and creams should be handled in a way similar to other dosage forms. Cosmetic preparation should be separate from medical preparation.

vii) The packaging and labeling department should be separated to prevent cross-contamination. Packaging lines should be separated so as to avoid product mixup. This area must be kept sanitary.

3) The introduction of ventilation, air filtration dust collecting and exhaust systems is necessary, especially in production areas in order to avoid any cross-contamination. Areas handling penicillins should have separate air handling system.

4) We recommend a sizable increase in the storage areas of all companies with clear subdivisions of the storage area. These subdivisions should include a quarantine area for incoming raw materials and packaging materials, rejected finished products, released components and in-process materials. In addition, more care should be taken in cleaning and maintaining these areas in order to avoid unsanitary conditions.

5) There should be written procedures for sanitation including assignment of responsibilities, scheduling, descriptions of methods, equipment and materials to be used in cleaning of the facilities and equipment, and procedures for the use of pesticides.

B. Equipment

Most of the production equipment used is foreign and is expected to meet international standards and specifications. We did not find any written procedures for equipment use, cleaning or maintenance in any company. Such written procedures need to be established and followed before the equipment is utilized for another batch. This should also include a record signed by the individual doing the work which indicates the type of drug being produced, the date and the time of starting and ending work. Persons doing the cleaning and maintenance of the equipment should also

sign a special record kept for that purpose. Such procedures are intended to prevent mix-ups and cross-contamination and would give the employees a greater sense of responsibility.

As indicated from the list in Appendix A, most of the companies have adequate production equipment. Such equipment, is underutilized especially the more automated machinery. Upon evaluation of the currently available equipment including discussions with the managment of each company, a list of equipment and instrumentation needed by each of the companies is shown in Appendix B. This list represents the aspirations of the companies to automate, improve and facilitate their production.

It is our opinion that the companies should unite or consolidate their activities to make the maximum shared use of the existing equipment. However, if the companies remain divided as they are now, some of the smaller companies are in immediate need of some production equipment. Such a need can be seen by comparing the lists in Appendixes A and B.

C. Quality Control Unit

The West Bank pharmaceutical companies lack a quality control

unit whose responsibility includes approving or rejecting drug products, packaging and labeling material. The units' authority should extend to reviewing all production records in order to check for any errors and to insure compliance with internationally acceptable standards. Throughout our onsite visits, we could not identify any unit having the overall authority to supervise product manufacturing in all its aspects. It is imperative that such a unit be established and have at its disposal adequate laboratory facilities for testing all components used in the manufacture of each product.

D. Laboratory

The companies meet the minimum standards for a quality control laboratory as specified by Jordanian law. In our opinion, the equipment available in those laboratories is inadequate and cannot possibly be used to analyse the wide variety of active ingredients incorporated in any one product. Thus, more sophisticated and advanced instruments must be introduced. There is a definite need for most of the companies to use their laboratories more efficiently and to establish their own methods of analysis. While most companies follow the procedures in the official compendia, such procedures are written mostly for the assay of one active ingredient. Any new methods developed should have

written procedures which include the accuracy, sensitivity and reproducibility of the method. We also found a need for written sampling procedures at the various stages of processing. Such information should be part of the master production file described later. There is also a need for stability testing of the final product. While most companies retain samples for a certain length of time, there are no written procedures and no evidence that the samples are tested according to a specifically maintained and executed schedule.

With respect to the laboratory, it is our recommendation that significant improvements in the instrumentaion need to be introduced. There should be more dependence and utilization of the laboratory to guarantee product quality. The following is a list of laboratory instruments which each company should acquire :

UV/Visible scanning spectrophotometer.

High pressure liquid chromatograph with variable wavelength UV detector.

Thin layer chromatography system.

Infra red spectrophtometer with quantitative capability.

Electronic analytical balances.

Moisture determination apparatus

Tablet disintegration apparatus

Tablet friability tester

Dissolution rate tester.

Laminar flow hood.

Microscopes.

Zone reader

E. Qualifications

The personnel engaged in all aspects of manufacturing and quality control lack proper qualifications and training. Table 2 indicates the approximate number of employees and number of chemists and pharmacists in each company. It can be concluded that chemists and pharmacists represent about 12% of the total working force. We believe that such a number is low and should be increased to insure better quality and efficacy of the products.

F. Control Of Components

There is a need for procedures describing receipt, identification, storage, handling, sampling, testing and approval or rejection of components, drug products, containers and closures. Special testing procedures for sterile products such as eye drops and ampules should also be documented

and implemented. In addition, tests on the properties of tablets and capsules need to be established and strictly followed. Such tests include tablet hardness, and friability, disintegration and dissolution rates where appropriate for tablets, capsules, and suppositories.

Records and record keeping should be vastly improved. Duplicates of all such records should be stored both at the laboratory and in the batch production and control file for future reference.

We understand that raw material is tested prior to use in most companies but that in certain cases the company depends on the certificate of analysis provided by the manufacturer of such component. In our opinion, raw materials have to be identified and analyzed in the company to check for any possible deterioration as a result of exposure to excessive heat and humidity during transport. In addition, containers and closures should be checked to determine if they conform to the company specifications. There should also be quarantining facilities for untested or rejected components.

G. Records and Documentation

During our site visits, it was obvious that the companies lack an organized and adequate record keeping and documetation system. All the companies keep some records of the

products, batches, laboratory control results, and distribution records. However, it is our opinion that such a system is neither well organized nor adequate. The following sections represent a list and description of some of the various files, records and documents which each of the companies needs to introduce, organize and make readily available for inspection.

i) Production and Control Procedures :

This file should include written procedures and all reasonable precautions taken to assure that the product has the desired strength, quality, purity and identity. Procedures dealing with weighing and measuring of components, addition of ingredients used during processing, identification and labeling of containers, use of control numbers, calculation of yield, equipment identification, and sampling and tests to be applied in process are to be included. In additon, precautions to avoid microbiological contamination or cross-contamination and time limitations for the completion of each phase in production are to be included. An additional section to this file should include packaging and labeling controls to insure no mix-ups in the final product. The introduction of such a document and the implementation of its procedures should provide for better control and guarantee the quality and efficacy of the product.

ii) Master Production and Control Records:

A master production file for each drug product and each batch size should be prepared in order to guarantee uniformity from one batch to another. The information in this file should include name and strength of the product, weight of each active ingredient per dosage unit and the total weight, list of components, a statement of the theoretical weight at appropriate phases of production, and the acceptable theoretical yield. In addition, the file should include a description and sample of all packaging and labeling material, and a complete description of sampling and laboratory procedures from the various phases of production, as well as any precautions to be taken.

iii) Batch Production and Control Records:

While some of the companies provided us with a production sheet, such a sheet is not adequate. This record should be an accurate reproduction of the master production file corrected for any deviations in amounts or weights for a particular batch. Any such file, including changes in it, has to be checked, dated and signed independently by two competent individuals. In addition, this record should include documentation that each of the significant steps has been properly executed. This information should be signed

by one person and verified by a second, and include weighing, mixing, sampling, quality control laboratory results, yields, control of the packging and labeling process. In addition, it should account for any deviations and investigations made during processing and should include the identification of the persons performing and checking each significant step.

iv) Complaint File:

Written procedures describing the handling of written or oral complaints should be established and documented. The role and function of the various units in such a complaint is to be specified. It should include the details of any investigation conducted and the measures takes as a result.

TRAINING CENTER

Based on our visits, we believe that the companies cannot provide adequate facilities for a training program on their premises. Birzeit University has established a Center for Environmental and Occupational Health Sciences whose activities include quality control analysis of marketed pharmaceuticals and assays of environmental samples.

Birzeit University is an independent institution which is

in close proximity to the seven West Bank pharmaceutical companies and the Center has adequate and modern facilities both for demonstrations and for training personnel in laboratory quality control methods. Therefore, we believe that the Center for Environmental and Occupational Health Sciences at Birzeit University is capable of offering a training program. Such a program could include aspects of industrial pharmacy, laboratory quality control and review of good manufacturing practices.

The program is directed towards individuals with college training. It can be divided into two major parts :

A. Practices of Industrial Pharmacy.

B. Laboratory Quality Control Methods.

Any interested person can take either or both parts, in addition to a review of good manufacturing practices. An outline of the programme is presented below and is designed for five-day course which includes reading materials, presentations, demonstrations, and on hand laboratory experience:

A. Practice of Industrial Pharmacy

1- Formulation.
2- Stability of Pharmaceutical Products.
3- Quality Control and Record-keeping.
4- Tablet manufacturing.
5- Capsules manufacturing.
6- Emulsions + Suspensions.
7- Ointments & Creams.
8- Parenteral Preparations.

B. Laboratory Quality Control

1) Official procedures, standards and references.
2) Extractions & identifications.
3) Quantitative techniques:

a) Spectroscopy: i) Ultraviolet/visible.
ii) Infra-Red,
b) Chromatography Principles & Practice
i) Thin layer chromatography.
ii) Column Chromatography
iii) Gas Liquid Chromatography
iv) High pressure liquid Chromatography.

4) Tablet and Capsule Evaluation:

i) Friability.
ii) Disintegration.
iii) Dissolution.
iv) Variation in weight.

5) Microbiological Tests
i) Microbiological assays
ii) Microbiological testing of sterile products.

C. Review of the Good Manufacturing Practices.

The Center for Environmental Health Sciences currently has two PhD's, Dr. Simon Kuttab and Dr. Ramzi Sansur, along with 2 B.Sc. Technicians. Another M. Sc. Technician is expected soon. In addition, it can draw on expertise from within and outside the University to offer a well-rounded, useful training program.

The administrationof such a program can be the responsibility of the Center and of Birzeit University. Such a program would be highly useful and is needed in order to upgrade the quality of products and the overall development of the West Bank pharmaceutical companies.

PHARMACEUTICAL PRODUCTION IN GAZA STRIP

Gaza provides a lucrative market for West Bank business in general, and the pharmaceutical industry is no exception. An average of 18 - 23% of the production of each of the seven West Bank pharmaceutical firms is sold in the Gaza strip. Our interviews indicated that between 60 - 70% of the total drugs sold in Gaza are from the West Bank manufacturers, while about 20% are Israeli and 10% foreign imports.

The reaction of the West Bank firms to the idea of starting pharmaceutical production in Gaza strip has been negative throughout. The reason is that they feel they are adequately covering the Gaza market and that there is no need for additional drug firms in the occupied territories. They favour the existence of a smaller number of firms, less competition and more specialization. They also complained that the Israeli drug firms use agressive selling tactics in Gaza by offering large bonuses for pharmacies. This was not evident during our interviews. It seems that Israeli drug marketing practices have been toned down over the last year. Information relayed to us about uncontrolled drugs being sold in Gaza appears to be unfounded.

The general feeling among political forecasters is that the

future of Gaza, in case of any settlement of the Arab - Israeli conflict, is unclear. Also, the geographic situation of the strip makes it more difficult to transport goods at certain times when the Israeli occupation forces impose curfews or travel bans to and from Gaza. Hence the supply of pharmaceuticals can easily be cut at the will of the occupiers. This and the lucrative business aspect are two of the reasons behind the move to start pharmaceutical production in the Gaza strip.

Gaza, with a population of 500,000, about 300 practicing medical doctors and 60 pharmacies, may constitute a good market for any pharmaceutical firm. Unfortunately the situation is not as simple as it looks due to the tough competition that any Gaza pharmaceutical firm will face from West Bank, Israeli and foreign competitors.

Many attempts were made, since 1972, to start pharmaceutical production in the Gaza strip but failed due to the difficulties of obtaining a licence. Two licences were finally issued this year to the following firms:-

1) Gaza Pharmaceutical Co.
   headed by Mr. Usama Al - Rayyashi, B.Sc. Pharmacy, Cairo University.

2) Medical and Chemical Arab Supply Co.
   headed by Mr. Mohammad Ali Salha, B. Sc. Pharmacy and Diploma in Industrial Pharmacy and Chemical Engineering, Cairo University.

Both have acquired buildings to start their companies, and the Medical and Chemical Arab Supply Company is beginning to equip its factory with machinery.

The two companies intend to sell shares in the market but want to limit then to medical doctors and pharmacists. The Medical and Chemical Arab Supply Co. intends to have a capital of one million Jordanian Dinars. Its present building site has a total area of about 300 m^2 of which 185 m^2 is devoted to production and quality control and the remainder to offices and storage facilities. We observed the presence of machinery such as a polymixer and were told that liquid, powder and ointment filling machines were on the way.

Gaza strip has the expertise and the needed capital to start drug production. The two individuals currently establishing the firms in Gaza are reasonably qualified. The percentage sales of the West Bank products in Gaza exceeds 60%. Thus the establishment of any pharmaceutical firm in Gaza will economically affect the currently existing West Bank firms and may also affect the sales of Israeli and foreign products. Consideration of the geographic location of Gaza and its obscure political future justifies the need for the establishment of pharmaceutical firms in a way to become self-sufficient and less dependent on outside products. Such a step might also help the area economically

and provide jobs for a number of people.

However, the situation existing among the West Bank firms with respect to coordination of activities is likely to repeat itself in Gaza. The two licenced firms seem to be working independently with no coordination among themselves and with the West Bank firms. This situation will result in the creation of tough competition between the two firms and with the West Bank firms.

SUMMARY

The aim of this study was to evaluate the West Bank pharmaceutical sector and to work out recommendations that will help in upgrading their finished products as well as consolidating their activities.

The seven firms manufacture over 690 different products of which a small percentage is cosmetics and aerosols. Their facilities vary in area and extent of organization. Most companies have adequate equipment to meet their present needs.However, there is an immediate need for additional laboratory instruments to better control their products.

Most physicians, pharmacists and other concerned individuals interviewed had complaints about the poor quality and low efficacy of some products. All agree that there were improvements in the last two years.

The companies do not produce some classes of drugs such as cardiovascular preparations, enzymes and hormones which are supplied by Israeli and foreign manufacturers. Such drugs may not be profitable to manufacture or the companies cannot compete with the equivalent non West Bank drugs.

Consolidation of activity and possible unity is essential to the continued existance of the companies due to having a small competitive market as well as the current economic slump.

Guidelines for improvement have been presented which mostly center on better plant layout, better record keeping and documentation of every step followed in production, market follow-up and better control of their products.

An intensive training programme has been presented which can be sponsored by the Center for Environmental and Occupational Health Sciences at Birzeit University.

Two pharmaceutical companies have obtained licences to start drug production in the Gaza strip. They are, currently organizing and equipping to start production.

CONCLUSION

In this report we have attempted to present an objective evaluation of the firms. It should be understood that any comments or criticisms represent our own point of view and conclusions. None are directed towards any one company. In addition, what applies to one company may not apply to another.

Some of the products may be competitive in their quality with their foreign equivalents but the latter enjoy the confidence of physicians, pharmacists and the public as a whole. It is a fact that none of the companies are ideal or can compete with international companies in terms of organization and strict controls.

We are concerned about the degree of in-process and final quality control of the finished product and their stability and shelf life. When dealing with drugs we are dealing with life and, most importantly, human beings. Thus we cannot afford to have any substandard product on the market at any time.

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Eastern Chemical Co.
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APPENDIX A

List of Available Equipment

Jordan Chemical Laboratory Co. Ltd.

Tablets and Capsules

Automatic tablet filling machine.
Fluid Bed Dryer.
Automatic Rotary Press.
Tablet & capsule counter (2)
Granulator.
Capsule filling machine.
Coating pan (2)
Capsule inserter.
Capsule tightening machine.
Dragee counting and filling machine.

Liquids

Simplex filling apparatus
Bottle washing and drying machine.
Washing and filling machine.
Vacuum filling machine
Press filter.

Sterile Products

Reaction vessel for sterile products.
Bidistiller
Ampule printing machine
Millipore filter.
Ampule filling and sealing machine.

Ointments, Creams and Cosmetics

Tube filling machine.
Colloid mill.

Suppositories

Mixing machine for suppositories.

Jordan Chemical Laboratory Co. Ltd.
(Cont.)

Packing

Over wrapping machine.
Strip capsule packing machine.
Blister package machine.

Others

Spray washing equipment machine.
Mini sabra machine.
Air compressor.
Steam generator.
Powder filling machine.

Laboratory

Analytical balance.
U.V. Spectrophotometer.
Melting point apparatus.
PH meter.
Polarimeter.
Refractometer.
Disintegration time tester.
Centrifuge.
Visible light spectrophotometer.
Lovibond nesslerizer.
Muffle furnace.
Incubator.

Palestine Medical Co.

Tablets and Capsules

Tablet press small.
" " large (2)
" " deduster.
Small granulator.
Large granulator.
Tablet coating machine. (2)
Large mixer. (3)
Capsule sorter.
Capsule filling and closing machine.
Capsule counting machine.
Automatic capsule filling machine.
Large capacity coating machine.
Fluid bed dryer.

Palestine Medical Co.
(Cont.)

Automatic capsule filling machine.
Small mixer. (2)
Tablet machine.
Tablet counting machine.
Medium size mixer.

Liquids

Liquid filling machine. (large)
Liquid filling machine. (small)
Small and large mixer.
Bottle sorter.

Sterile Products

Ampule printing machine.
Millipore filter.
Autoclave.
Ampule filling machine.
Vial filling machine.
Vial closing machine.
Ampule washing and sterilizing unit.
Dry autoclave.
Steam pot.
Eye drop filling machine.
Automatic ampule machine.
Automatic vial machine.

Ointments and Creams

Ointment filling machine.
Large ointment mixer.
Small ointment mixer.
Manual ointment filling machine.
Tube filling machine.

Suppositories

Suppository machine.
Suppository packing machine.
Powder and suppository filling machine.

Packing

Small packing machine.
Labeling machine.
Sealing machine.

Palestine Medical Co.
(Cont.)

Others

Powder mill.
Small oven. (2)
Large oven.
Electric heater.
Small pump.
Large and small distillation apparatus.
Steam generator.
Large and small compressors.
Large washing machine.
Moving belts. (2)
Roller mill.

Laboratory Products

Magnetic stirrer with hot plate. (2)
UV/Vis. scanning spectrophotometer.
UV/Vis. spectrophotometer.
Analytical balance. (3)
PH meter.
Melting point apparatus.
Centrifuge.
Shaking water bath.
Oven.
Incubator.

Birzeit Pharmaceutical Co.

Tablets & Capsules Products

Tablet press.
Fluid bed dryer.
Drum mixer.
Granulator.
Varimixer.
Turbomixer.
Powder mixer.
Fitz mill (Powder)
Semi - Automatic capsule filling.
Automatic capsule filling.
Automatic spansule and capsule filling.
Single punch tablet press.
Tablet coating and polishing machine.

Birzeit Pharmaceutical Co.
(Cont.)

Liquids

High viscosity pump.
Colloid mill.
Bottle washing machine.
Bottle filling.
Bottle capping.
Laminar flow oven.
Bi-distiller.
Russel strainer.
Steam generator.
Liquid filling machine (E/D)
Semi automatic bottle capping.
Liquid filling apparatus.
Collovelox mill.

Ointments & Creams

Double jacket container (250 lt.)
Double jacket mixer (200 lt.)
Ointment and cream filling.
Ointment and liquid pump.
Homogenizer.

Sterile Products

Millipore filter unit.
Bench laminar flow hood.
Double door oven.
Vial filling machine.
Vial and ampule printing.
Liquid vial filling machine.
Liquid filtration apparatus.
Roof laminar flow.
Ampule testers (2 units)

Suppository Products

Suppository filling machine.
Suppository sealing machine.
Water bath.

Packing

Noak blistering.
Plastic sealing unit.
Automatic labeling.

Birzeit Pharmaceutical Co.
(Cont.)

Others

Electric oven.
Water softner.
Water boiler.
Powder suction.
Dehumidifier.
Powder deduster.
Mixer under vacuum.
Air compressor.
Dehumidifier unit.
Powder filling.
Powder filling (Semi-Automatic)

Laboratory Products

Tablet hardness tester.
Metler balance. (2)
Tripple beam balances. (3)
Double pan balances. (2)
U.V./Visible spectrophotometer.
PH meter.
PH meter.
Flask shaker.
Centrifuge.
Melting point apparatus.
Polarometer.
Tablet disintegrator.
Thermoplate heater and stirrer. (2)
Oven.
Furnace.
Millipore pumps.
Animal room.
Rabbit cages.
S.S. conditioners for rabbits.
Rabbit thermometer (electrical)
Plastic mice cages.
Oven.
Microscope.
Antibiotic zone reader.
Incubator.
Autoclave.
Water bath.
Millipore filtration unit.

Balsam Medical & Chemical Work Co. Ltd.: Not available.

Eastern Chemical Co.

Tablets and Capsules

Manual capsule filling machine.
Automatic capsule filling machine.
Granulator.
Dosing machine for antibiotics.
Rotary tablet press.
Sugar coating machine.
Powder mixing machine.

Liquids

Colloid mill.
Liquid filter.
Liquid filling machine.

Sterile Products

Eye drops filling machine.
Laminar flow hood.
Ultra violet water sterilizer.
Millipore filter.

Ointments & Creams

Tube filling machine.
Automatic ointment filling machine.

Packing

Blister packing machine.

Others

Powder filter.
Powder filling machine.
Electronic thermometer.
Manual suppository machine.
Strainer.

Laboratory

Ultra violet spectro-photo-meters.
PH meter.
Water baths.
Test tube shaker.
Magnetic mixer.
Incubator.
Metallic sterilizer.

Gama Chemical Company

Tablets and Capsules

Single punch tablet press.
Mixer drum.
Capsule filling machine.
Counting and filling machine.

Liquids

Liquid filling machine.

Ointments & Creams

Tube filling machine.

Aerosols

Semi automatic aerosol filling machine.

Packing

Blister packing machine.

Others

Drying oven.

APPENDIX B

List of Needed Equipment

JORDAN

PRODUCTION	LABORATORY
Powder mixer.	Infra red spectrophotometer.
Automatic labeling machine.	
Carton coder.	Gas liquid Chromatograph.
Carton packing machine.	

PALESTINE

PRODUCTION	LABORATORY
Rotary table press.	Gas liquid chromatograph.
Automatic carton coder.	
Sieving and straining machine.	
Double distiller.	
Packing machine.	
Automatic labeling machine.	

JERUSALEM

PRODUCTION	LABORATORY
Mixer.	Microscope.
Sifter.	Gas liquid chromatograph.
Granulator.	Vacuum pump.
Oscilator.	Melting point apparatus.
L/S tablet coating machine.	Infrared spectrophotometer.
Effervescent tablet machine.	
Automatic liquid filling machine.	
Automatic heavy suspension filling machine.	
Automatic belt for syrup.	
Automatic plastic tube sealing machine.	
Ampule printing machine.	
Automatic carton coder.	
Printing unit for blister packing machine.	
Automatic feeder for blister packing machine.	
Belt for production.	
Electric generator.	

List of Needed Equipment
(Cont.)

PRODUCTION	LABORATORY
BIRZEIT	
Rotary tablet press.	Thin layer chromatography unit.
Automatic carton coder.	Laminar flow hood.
Electric generator.	UV./Visible scanning spectrophotometer.
	Dissolution rate apparatus.
	High pressure liquid chromatograph.
BALSAM *	
—	— —
EASTERN	
Suppository machine.	UV/Visible scanning spectrophotometer.
Spansule unit for capsule filling machine.	Senitive electronic balance.
GAMA	
Automatic capsule filling machine.	Tablet disintigration tester.
Rotary tablet press.	Tablet hardness tester.
Granulator.	Moisture determination apparatus.
Accurate scales.	Water bath.
	Incubator.

* The general directordid not provide us with the requested information.

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1. Introduction

Energy consumption in developing countries is dominated by petroleum in both petroleum exporting and petroleum importing countries. The rising price of oil over the last decade has created very obvious difficulties for developing countries to meet their energy requirements in line with the overall growth rate of their economies.

The acquisition and management of technology and skills is therefore a fundamental issue of petroleum enterprises in developing countries for the operation of their refineries at maximum efficiency.

In view of the wide disparity of technical, managerial and administrative experience among petroleum enterprises and given the need for technology transfer and training experience by developing countries, the United Nations Symposium on State Petroleum Enterprises, held in Vienna, Austria, March 1978, stressed the importance of the establishment of closer links among petroleum enterprises. It was pointed out that national petroleum refineries in developing countries will doubtlessly not be less successful than multinational petroleum companies if their technical personnel were provided more frequent opportunities, possibly on a continuous basis, to exchange experience and information among themselves on the problems and constraints of their refineries, and keep themselves abreast of the latest developments in petroleum refining.

In line with these recommendations, UNIDO in close co-operation with the OPEC Fund, the national Petroleum company of Austria, OMV, and the Austrian Federal Economic Chamber organized its first workshop in the field of petroleum refining "Workshop on Petroleum Processing", held in Vienna from 21 to 30 April 1981. The workshop was intended particularly for those developed countries (LDCs) whose state-owned or state-controlled petroleum refineries are in urgent need of assistance to improve their efficiency and competitiveness.

This workshop programme included the following subjects:

- refinery personnel organization
- personnel training
- refinery operation
- utilities
- maintenance
- environmental control and energy conservation
- trouble shooting.

These subjects were discussed with a view to providing assistance to refinery engineers mainly at a managerial level. Although the objectives of the workshop were largely achieved, it was felt that future workshops should be arranged annually, if possible.

This, combined with the need for more in-depth discussion on selected subjects led to the arrangement of a second workshop held from 3 to 19 May 1982, the programme of which focussed only on three topics:

- trends in petroleum processing
- production planning
- energy management.

As participants and sponsors of the preceding two workshops repeatedly pointed at the lack of sufficient experience in maintenance and plant inspection in petroleum refineries of developing countries, a workshop on these topics was organized, which took place in Vienna, Austria, from 5 to 23 September 1983.

The technical programme of the two preceding workshops as well as of this workshop, was conducted by OMV, Austria, in their refinery at Schwechat, and included lectures, discussions and plant visits.

For over two decades Austria has owned and operated a successful petroleum enterprise, covering the whole range of oil and natural gas industry, from exploration and production to refining and distribution. OMV has erected a modern, efficient refinery at Schwechat to replace the many small, inadequate refineries that existed before 1955 at

the oil fields situated in Eastern Austria. The Schwechat refinery is reported to be the largest Central European refinery with a yearly throughput capacity of 14 million tons. The presence of multinational corporations has forced OMV to always apply the most modern processing methods, the latest technical knowledge. It is believed that the experience gained by OMV could provide useful guidelines for developing countries.

2. The Workshop

The organizers selected jointly 57 developing countries to be invited, among them 25 countries, including OPEC member countries, to attend the workshop entirely at their own costs. Candidates from the remaining 32 countries were requested to share 50% of their individual air travel cost, while daily subsistance allowance and tuition fees were borne by UNIDO. Invitation letters together with the workshop programme and aide-mémoire were sent to each Government through the UNDP office in the country. Selection of candidates was carried out jointly by the organizers based on the candidate's background and on information about his refinery, which the candidate was requested to provide by filling in a questionnaire.

While the participants of the 1981 workshop were mainly refinery directors and managers and of the 1982 workshop engineers and superintendents, the 1983 workshop was designed for refinery personnel specialized in maintenance and inspection, such as maintenance engineers, heads of workshops and plant inspection engineers.

Twenty-two suitable participants were selected for the workshop, ... 12 of them attending the workshop at their own cost (Annex I, list of participants).

2.1 Programme

As for the two preceding workshops, the technical programme ..... of this workshop (see Annex II), consisting of lectures, discussions, plant visits and visits to Austrian companies, was arranged by OMV, and conducted at their Schwechat refinery. OMV assigned about

12 engineers, many of them for the entire duration of the workshop, to prepare background papers and assist in the lectures and discussions. Lecture outlines, technical specific data and drawings were distributed to the participants each day. The lectures of the workshop programme ..... are summarized in Annex III.

The workshop was opened with a session at UNIDO, followed by a moderating session at OMV, where participants and OMV staff assessed further specific problems, which the participants would like to have included in the workshop programme. The closing session was intended for discussions on the workshop results and follow-up activities and recommendations on future co-operative programmes.

2.2 Opening Session

Mr. D.G.A. Butaev, Director, Division of Industrial Operations, UNIDO, pointed out in his opening speech the important role played by petroleum refineries in the economies of developing countries and the need for concrete proposals for raising their efficiency and competitiveness. He went on saying that exchange of experience and information and the establishment of closer working relationships among refinery personnel were useful elements for the achievement of that objective. As the response to invitations of this year's workshop was particular good, Mr. Butaev said that the subject of this workshop together with high quality of lectures, presentation and discussion arranged by the staff of OMV must be responsible for the enthusiasm shown by the developing countries in this year's workshop.

The next speaker was Mr. F. Schmid, Alternate Permanent Representative of Austria to the United Nations in Vienna, who emphasized the importance his Government attaches to the co-operation with UNIDO in the implementation of practical work supporting the promotion of industrial development in developing countries. Experience exchange, as a form of training, he said, was of paramount importance. He expressed the hope that in the field of petroleum refining, Austria, through its national petroleum company OMV, would successfully assist in the improvement of maintenance and plant inspection of refineries in developing countries.

The floor was then given to Mr. Awni Al-Ani, Assistant Director General, OPEC Fund for International Development, who referred in his speech to the experience the OPEC Fund had gained in its own projects in developing countries and the effect that the lack of maintenance had on the outcome of these projects. He also stated that workshops of this kind were important in view of the high operation costs of refineries in developing countries due to bad maintenance and in view of the need for improvement in that field. He was confident that expertise offered by OMV would be very useful and beneficial for the workshop participants.

OMV was represented at the opening session by Mr. Herbert Kaes, Director General, who drew the attention to the 1978 UNDTCD Symposium on State Petroleum Enterprises, Vienna, when the idea for this series of refinery workshops was proposed by the then OMV Director General, Mr. Ludwig Bauer. Mr. Kaes expressed the feeling that the importance of maintenance and plant inspection for petroleum refineries was too often underestimated. He added that this issue was equally important for petroleum refineries of industrialized countries as indicated by the results of the latest World Energy Conference (1983).

The opening session concluded with the speech given by Mr. Heinrich Lederleitner from the Austrian Federal Economic Chamber, an organization which supports through the Austrian Government several programmes implemented by UNIDO, especially in the field of petroleum industries

as explained by Mr. Lederleitner. He then gave a brief outline on the objectives and the structure of his organization. The Austrian Federal Economic Chamber is the top organization representing through its 80 trade delegations in foreign countries, Austrian industries, trading companies, tourism, transport and banks. The organization is equally involved in the export from Austria as in the import to Austria. He mentioned that with his organization's support, the UNIDO Investment Promotion Service for Austria for the intensification and generation of industrial investment projects had been recently established.

2.3 Closing Day

The morning of the closing day was devoted to a visit to the OPEC Fund for International Development in Vienna, where the participants were introduced by Mr. Benamara, Director of Information, to the organization and work of the OPEC Fund. He explained that the OPEC Fund receives voluntary contributions from its 13 member countries, which form the financial basis for the Fund's technical co-operation and lending programmes in developing countries. Mr. Benamara added that about 50% of the loans and grants of the Fund's projects were in the field of energy, mainly for least developed and food deficient developing countries.

During the subsequent discussion several questions were raised concerning loan and grant application and administration. The OPEC Fund replied that technically and financially sound project proposals were the main elements for the decision making process on which selection of countries applying for assistance from the OPEC Fund were based.

During the closing ceremony, Mr. H. May, Deputy Director of the Division of Industrial Operations, UNIDO, thanked all co-organizers and participants for their efforts towards the success of the workshop. He pointed at two major problems: How to promote and maintain a continuous exchange of information among the petroleum refineries in developing countries themselves and with OMV and, secondly,

how to improve the efficiency of refineries in the developing countries and help solve them the many problems that they are facing. Furthermore he stressed the need for co-operation among the various national and international organizations in pooling their resources for the implementation of programmes recommended during the workshop.

Mr. Harald Miltner, Advisor to the Permanent Representative of Austria to UNIDO commented in his speech on the usefulness of such workshops, while Ms. Najib on behalf of the OPEC Fund for International Development complimented the participants and organizers on the success of the workshop.

In his closing address, Mr. Herbert Kaes, Director General of OMV, mentioned the mutual interest and benefit this type of workshop offered to the participants as well as to the organizers. He emphasized the importance of environmental issues for petroleum industries. He added that Austria's environmental policy has forced legislation to enter into the preparation of laws related to air and water pollution standards and control, which will become effective in the near future, and place Austria among the leading countries in this field.

The Austrian Federal Economic Chamber was represented by Mr. Karl Haas who said that his organization gladly contributed to this workshop not only financially but also through providing contacts with manufacturers of machinery and equipment for petroleum refineries. He referred to the mutual usefulness of such contacts.

Mr. Tadikonda Virabhadra Prasad, India, spoke in the name of all workshop participants expressing appreciation to the organizers and the sponsors of the workshop for their efforts made towards the success of this workshop. He stressed the importance of the workshop topic for developing countries and commented on the high quality of the technical programme as presented by OMV.

Preceding the closing ceremony, a round table discussion with the participants, the organizers and some of the lecturers was organized, to evaluate the workshop programme and to establish recommendations for future co-operation in this field. The workshop conclusions and recommendations are described in the following chapter.

3. Evaluation and Recommendations

This year's workshop was the third in a series of workshops dealing with the various aspects of petroleum refinery industry organized by UNIDO. The topic Maintenance and Plant Inspection must have been one of the reasons for the good response to the invitations to the workshop. From the 22 selected workshop participants, 12 participants came at their Government/organization's cost. The other 10 participants who attended the workshop at UNIDO project cost had to contribute 50% of their air travel fares.

It was generally agreed that the objectives of the workshop had been largely achieved and that this year's technical programme was of great benefit to the maintenance and inspection engineers from developing countries.

It was felt by the participants and the staff members of the sponsoring organizations, who were closely involved in the preparation and conduct of the workshop, that the results of the workshop were a valuable contribution towards furthering the exchange of practical experience and know-how in petroleum refining.

During the preceding two workshops and also during this workshop, participants emphasized the importance of arranging similar workshops annually, if possible. This type of technical consultation plays a significant role for refinery managers and engineers from developing countries to promote co-operation among themselves and/or consult specialist staff on specific problems.

The need for establishing an experience exchange group on the problems of petroleum refineries in developing countries was stressed by a number of workshop participants. This was supported by the sponsoring organizations, as such experience exchange groups exist in industrialized countries and have proved to be of considerable benefit for the participating petroleum refineries. Staff from OMV, Austria, mentioned that prior to the meeting of such an experience exchange group, a problem catalogue is presented to its committee, which then prepares proposals for solution for discussion at the meeting. The participants from India, Venezuela and Nigeria mentioned that on a national and sometimes also on a regional level their refineries had already taken steps towards setting up such experience exchange groups. But all participants agreed that UNIDO should follow up this idea, define the terms of reference for such an experience exchange group and mobilize resources for its materialization. It was recommended that at the beginning the experience exchange group should concentrate on issues related to maintenance and plant inspection, but later broaden its scope of activities to other topics of petroleum refining such as

- process performance data,
- energy conservation schemes,
- environmental control,
- inspection of equipment and corrosion problems,
- rotational equipment failure analysis and predictive maintenance,
- training methodologies and programmes for operators/inspectors/maintenance personnel,
- safety aspects,
- application of computerized process control.

The question arose whether maintenance and plant inspection should be separately dealt with at different workshops. Most of the participants agreed that these two topics are interrelated and should therefore not be separated.

There was a short discussion on more company/plant visits and practical demonstration work during the workshop programme. It was however pointed out that this would be a little outside the scope of the programme.

Some participants invited UNIDO to compile a list of suppliers for commonly used parts. It was indicated by UNIDO that in view of existing trade directories and catalogues, such compilation appeared not very meaningful.

In addition, the request for more specialization in the programme, e.g., corrosion and inspection, was briefly discussed. It was pointed out that it was difficult for the organizers to design a programme which meets the exact expectations of each participant. There was general agreement that very special problems were dealt with better by an experience exchange group.

UNIDO's technical assistance programme in the energy sector and the framework under which such assistance can be obtained were introduced to the participants during the workshop. Certain requirements were expressed in the field of training, mainly for very specialized courses, in addition to experts services and equipment supply.

ANNEX I

List of Participants from Developing Countries

Country	Name and address of participant
Algeria	Mr. Oulmi Mohamed SALAH Engineer Sonatrach
Angola	Mr. Adao Mauricio KIALA Ambrosio Inspector of Installations Petrangol Refinery Rua Rev. Agostinho Pedro Nr. 20-2-A APT 22 Luanda, TELEX: 3329 PETMAT/AN 3033 PETREF/AN
Burma	Mr. Myint Oo Maintenance Engineer Petrochemical Industries Corp. 33, York Road Rangoon, TELEX: 21329 BM PECHEM
China	Mr. Xiaolei ZHANG Engineer/Maintenance Management China Petroleum Processing Corp. Liu Pu Kang Beijing, TELEX: 22312 PCPRC
Ethiopia	Mr. Yigzaw MEKONNEN Engineer Head Ethiopian Petroleum Corp. Addis Ababa, TELEX: 21054
Ghana	Mr. Frank Godfrey ESSIAW Assistant Technical Manager Ghaip Oil Refinery P.O. Box 599 Tema
India	Mr. Tadikonda Virabhadra PRASAD Specialist Manager Engineers India Ltd. 4, Parliament Street New Delhi 110001, TELEX: 031-3827
Ivory Coast	Mr. Honoré KHISSY BEYNIOUAH Assistant to Chief of Technical Department Société Multinationale de Bitumes (S.M.B.) 12 BP 622 Abidjan, TELEX: 42 539
Libya	Mr. Bashir Mohammed NAJJAR Inspection Division Head Azzawiya Oil Refining Co. P.O. Box 645 Tripoli, TELEX: 30423

List of Participants from Developing Countries (Cont...)

Country	Name and address of participant
Nigeria	Mr. J.A. AKANDE Mr. P. EGHO National Petroleum Corp.
Oman	Mr. Redha Hassan ABDUL-RASOOL Assistant Maintenance Engineer Oman Refinery Company LLC P.O. Box 6568 Ruwi, TELEX: 3123 ORC MCT
Philippines	Mr. Ruben Fulgencio DE LEON Assistant Maintenance Manager Mr. Juan Wilfrido C. BONOT Planning Engineer Bataan Refining Corp. 7901 Makati Ave., Makati MM Metro Manila TELEX: PNOPH 633667 PNOC PN
Sri Lanka	Mr. Don Patrick Eugene Nimal RAJAPAKSA Manager, Mechanical Maintenance Ceylon Petroleum Corp. Refinery P.O. Box 11 Kelaniya, TELEX: 21167 CEPETCO CE
Tanzania	Mr. Lot M.A. CHIHOMA Technical Planning Officer Tiper Co. Ltd. Kigamboni Refinery Site Dar-es-Salaam, TELEX: 41005
United Arab Emirates	Mr. Abdullah Mohammad AL JENAIBI Jr. Mechanical Engineer Abu Dhabi National Oil Company Khalifa Street, Adnic Building Abu Dhabi, TELEX: 24232 ADNOTP EM
Uruguay	Mr. Walter DURA REY Mechanic Industrial Engineer A.N.C.A.P. Luis de la Peña 1000 Montevideo, TELEX: UY 6692
Yemen, P.D.R.	Mr. Mohammed HAMEED ABDO Plant Inspection Engineer Mr. Mohsen Ali SAEED Planning, Programming and Records Engineer Aden Refinery Company P.O. Box 3003 Aden TELEX: 2213 ADRFINRY

List of Participants from Developing Countries (Cont....)

Country	Name and address of participant
Venezuela	Mr. Alberto BEUSES Amuay Refinery Deputy Manager Lagoven, S.A. (Petróleos de Venezuela) 527 Tachira Judibana - Falcón TELEX: 54169
Zambia	Mr. Hubert Mubanga BWALYA Chief Engineer Indeni Petroleum Refinery Co. Ltd. Bwana - Mkubwa Ndola, TELEX: ZA 34221

ANNEX II

1. Workshop Programme

5 September 1983

9:00 OPENING SESSION AT UNIDO

Chairman pro tem: Mr. M. Maung, Industrial Development Officer, Chemical Industries Branch Division of Industrial Operations, UNIDO

Opening Speech: Mr. D.G.A. Butaev, Director, Division of Industrial Operations, UNIDO

Speeches by: Dr. Franz Schmid, Alternate Permanent Representative of Austria to UNIDO

Dr. Awni Al-Ani, Assitant Director-General The OPEC Fund for International Development

Dr. Herbert Kaes, General Director ÖMV Aktiengesellschaft

Dr. Heinrich Lederleitner, Director Austrian Federal Economic Chamber

11:00 ARRIVAL AT ÖMV REFINERY SCHWECHAT

- Welcome by the Refinery Manager — Cech
- Introduction of all associates participating in Workshop — Cech
- Presentation of the Workhop Programme
- Brief introduction to ÖMV AG — Smejda

14:30 VISIT THROUGH THE REFINERY

6 September 1983

9:00 MAINTENANCE	Lecturer/Moderator
- General Overview/Introduction	Maier/Miglitsch
- The Total Maintenance Function	Maier/Miglitsch

12:00 LUNCH in the Refinery

		Lecturer/Moderator
13:00	- Shutdown planning and scheduling (network technique)	Maier/Miglitsch
	- Maintenance internally or externally (by contractor)	Maier/Miglitsch

7 September 1983

9:00	- Maintenance of equipment, compressors, turbines	Miglitsch/Kloyber
12:00	LUNCH in the Refinery	
13:00	- Maintenance of process pumps	Sieh/Miglitsch
	- Maintenance of instrumentation (pneumatic, analysis equipment)	Kloyber/Miglitsch

8 September 1983

9:00 MAINTENANCE

- Maintenance of instrumentation (process analysis equipment) — Kloyber/Brantner

MATERIAL SUPPLY

- Flow of information concerning spare parts — Kreisler/Brantner
- Spare parts ordering inside refinery and from outside suppliers — Kreisler/Brantner

12:00 LUNCH in the Refinery

13:00 MATERIAL MANAGEMENT

- Warehouse management
- Material handling — Brantner/Kreisler
- Material administration

Visit to OMV refinery warehouse.

9 September 1983

Reception at the Federal Economic Chamber of Austria and meetings with various companies and manufacturers of refinery-related equipment.

Visit to OMV's central workshop and warehouse.

10 and 11 September 1983 (Saturday/Sunday)

12 September 1983

9:00	- Corrosion problems in petroleum refineries - Scheduling equipment for inspection - Inspection methods - Deterioration and failure of equipment and its prevention - Question/Answer-Session on the above topics	Hornasek
12:00	LUNCH	
13:00	- Corrosion protection by organic layers (Paint). On-site demonstration in co-operation with the FERROPAN-Bautensch. Comp. - Lifetime of equipment - Detailed equipment inspection - On-stream inspection and special testing methods Part 1: Ultrasonics	Hornasek

13 September 1983

9:00	- On-stream inspection and special testing methods Part 2: Thermovision, acoustic emission - Practical demonstration of selected NDT techniques - Special Schwechat Refinery problems and their solutions - Filing and documentation - Visit to the ACOUSTIC EMISSION TRAILER with on-site demonstration in co-operation with TÜV-Vienna	Hornasek
12:30	LUNCH	
13:30	- Material standards - Pressure parts - High/low temperature service - Austrian pressure vessel code - NDT/DT testing regulations for materials - Question/Answer-Session on the above topics	Wischin (TÜV)

14 September 1983

	Visit to VOEST ALPINE steel mill	Smejda

15 September 1983

9:00	TROUBLE SHOOTING	
	- General considerations about equipment failures	Maier/Miglitsch
	- Turbo machines and pumps (Bentley system, predictive maintenance)	Miglitsch/Maier
12:00	LUNCH	
13:00	Field trip through selected units within the refinery.	

16 September 1983

9:00	MAINTENANCE ORGANIZATION and MAINTENANCE INFORMATION SYSTEM	Maier/Sieh
12:00	LUNCH	

17 and 18 September 1983 (Saturday/Sunday)

19 September 1983

	Material Economics and Computer Systems	Strauss/Klima

20 September 1983

9:00	Special problems raised by participants during moderating session	
12:00	LUNCH	
14:00	Afternoon at UNIDO	

21 September 1983

9:00	ATS (Analytical Trouble Shooting)	Huber
12:00	LUNCH	
13:00	ATS	Huber
15:30	Visit to SIMMERING-GRAZ-PAUKER	

22 September 1983

9:00	Training Maintenance Personnel	Schweng
	Planning of repair shops	Kielhauser
12:00	LUNCH	
13:00	Discussions of problems related to FCC	Weithofer
14:00	Summary and conclusion	

23 September 1983

10:00 Visit to OPEC Fund for International Development

12:30 LUNCH offered by OPEC Fund

14:00 Closing Session at UNIDO

Opening remarks for discussion on Workshop results and follow-up activities by Mr. M. Maung (Chairman)

- Participants' views on the programme
- Comments by the organizers
- Recommendations on future technical co-operation and follow-up activities.

15:30 Closing Ceremony at UNIDO

Chairman pro tem: Mr. M. Maung, Industrial Dev. Officer, Chemical Industries Branch Division of Industrial Operations, UNIDO

Closing speech by: Mr. H. May, Deputy Director, Division of Industrial Operations. UNIDO

Statements by: Mr. Harald Miltner, Counsellor Adviser to the Permanent Representative of Austria to UNIDO

Dr. Herbert Kaes
General Director
OMV Aktiengesellschaft

Mr. Karl Haas
Austrian Federal Economic Chamber

Dr. Tadikonda Virabhadra Prasad, India
Speaker for Workshop Participants

Award of Certificates

16:00 Reception at UNIDO

ANNEX II

2. Name and Function of Lecturers

a) Scientist

Prof. Dipl. Ing. Dr. Fritz PASS	Head: OMV Central Research and Development Department; Professor at Technical University, Vienna

b) OMV Headquarter Staff

Dkfm. Heimo HUBER	Head: OMV Training Department
Dipl. Ing. Peter KIELHAUSER	Assistant to Chairman of the Executive Board
Mag. Viktor KLIMA	Head: Concern Organization

c) Refinery Experts

Dir. Dr. Franz CECH	Refinery Manager
Ing. Josef MAIER	Head: Refinery Maintenance Department
Mag. G. BRANTNER	Deputy Commercial Manager
Ing. A. HORNASEK	Head: Refinery Inspection Department
Dipl. Ing. Dr. H. KLOYBER	Head: Instrument Department
Dipl. Ing. H. KREISLER	Asst. Technical Manager
Dipl. Ing. MIGLITSCH	Asst. Maintenance Manager
Dr. J. SCHWENG	Refinery Training Department
Dipl. Ing. H. SIEH	Maintenance Department

d) Affiliates/Consultants

Dipl. Ing. RAABER	TUV (Technischer Überwachungsverein) Technical Inspection and Control Authority

e) Organization

Mrs. L. SMEJDA	OMV Training Department, Foreign Trainees Section

ANNEX III

Abstracts of Le[illegible]es

1. Maintenance in Refineries - An Overview (J. Maier)

The rationalization measures taken in recent years within the processing industries have led to the construction of an increased number of units/plants in the production sector, resulting in a decrease of the production costs. At the same time, however, the cost of maintenance - a labour-intensive sector - has considerably increased. Therefore efforts are being directed towards minimizing the costs of maintenance to the lowest economically and technically acceptable level. This implies careful design of maintenance strategies and their implementation.

The management of a refinery has therefore to plan and establish appropriate maintenance policies. Modern maintenance requires interaction between many different working groups of a refinery and cannot be left with the maintenance department alone, which, together with the staff of the production plants, will carry out the required maintenance function as defined in an overall refinery maintenance policy.

2. Maintenance Functions, Policy and Strategies (J. Maier)

Maintenance as a whole comprises all personnel and activities involved in the maintenance of a refinery. Maintenance policy is geared towards minimizing maintenance costs and generally would allow expenditures only in cases where the output contributes to the safety of personnel and plant equipment, to the refinery profitability and to the implementation of Government, community or labour organizations regulations. As a general principle the following guidelines may be observed: refinery-wide awareness and responsibility for maintenance expenditures; reasonable approach in terms of safety, profitability, environmental control, energy conservation; improvement of the skills of maintenance and other staff.

The day-to-day maintenance decisions may be guided by the following considerations:

- Break-down maintenance: A given system breaks down due to a part which has become completely useless and therefore needs either repair or replacement. The latter requires spare parts stockage causing storage costs.

- Preventive maintenance: Based on the estimated lifetime of parts, a scheme for planned exchange of parts can be developed. With larger plant systems this requires special index card systems for control and, from a certain size of the refinery on, the assistance of a computerized part control, exchange and supply system.

- Predictive maintenance: Since today various test methods are available to check the status of plant parts on stream, failure of equipment can be predicted within a certain uncertainty range and repair programmes, production and procurement schedules can be set up accordingly. These measures are

based on comparative analysis of cost of repair of defective part and production loss weighted against the consequences caused by total break-down envisaged for the defective part. Scientific methods combined with empirial data and practical experience will assist maintenance managers in the decision-making process.

- Corrective maintenance: In cases of high frequency of damages which may reveal a defect in the construction, a solution for the improvement of such a construction must be found.

3. Maintenance through External Contractors (J.Maier)

Many refineries have maintenance work done through outside contractors. The extent to which external contractors are assigned for this work depends largely on local conditions, the maintenance policy of the refinery and technical security regulations. The decision for an engagement of an outside contractor is usually guided by the following considerations: provision of know-how not available within the refinery; repair/overhaul of plants; periodic requests for maintenance works to be contracted and establishment of a contract on a permanent basis; high work peak loads within the refinery and lack of own personnel; requirement of very special technical devices and skills for certain maintenance works. Maintenance management must decide at an early stage whether work should be done through contractors or whether additional investment and recruitment of personnel is more appropriate for satisfying maintenance needs.

4. Shut-down Planning and Scheduling (J. Maier)

Very special methods are necessary for shut-down operations of a plant, which must be carried out at the shortest time possible. This is efficaciously done through network planning and network analysis (critical path planning method). This implies the preparation of a detailed work programme involving the plant manager, field technician, plant technician, the inspection department and the stop planner. Network plans are established and analyzed. Personnel is usually recruited through contracting firms. The shut-down programme is supervised and monitored preferably by the stop planner. A very important phase is the evaluation of data after work has been completed. These data represent a good basis for future planning.

5. Maintenance of Equipment - Compressors, Turbines (H. Miglitsch)

Plant equipment such as turbines and compressors need special attention in maintenance and service, whereby one has to distinguish between reciprocating compressors and turbine compressors and turbines. Organization of the responsibility for staff concerned with service and maintenance depends on the size of the refinery. Engineers and workers have to be trained almost on a continuous basis. OMV has made the experience that for turbines and compressors periodic service is not necessary but recommends regular protocols for controls of machine performance data. Through the variation of these data malfunctions can be identified. Reciprocating compressors, however, will require maintenance work at regular intervals as recommended by the manufacturer, mainly due to the higher wear rate of many parts of this type of compressor system. Several examples for maintenance work during a planned plant shut-down are given.

The degree of vibration of rotary machinery is a very strong indicator for imperfect alignment, instable bearings, unbalanced rotors, etc. These causes for malfunctions must be destroyed. Therefore the many different types of bearings must be checked as well as the rotors (pumps, fans, electric motor rotors, compressors, turbines), and the influence of the settling of the foundation and of temperature difference.

Some special instruments exist such as alignment calculator, bolt extensiometer, pressure test/repair facilities for compressor valves. Particularly the extensiometer appears to be very useful as it is a means to determine the precise length of a bolt (ultrasonic) and therefore provides the basis for accurate calculation of the bolt preload. It also can be used for checking relaxation and helps to prevent thermal cycling, vibration, gasket creep, load cycles and joint failures.

6. Maintenance of Process Pumps (H. Sieh)

An important cost factor represents the maintenance of process pumps. Pumps repair costs are approximately 7% of the total maintenance expenditures of a refinery. Most of the pump failures originate from defects in the mechanical seals (70%), bearings and oil seals, corrosion, erosion, cavitation, etc. OMV has developed a number of proceedings to reduce these cost factors.

7. Maintenance of Instrumentation - Pneumatic, Electronic Instruments (H. Kloyber)

For the control of approximately 6000 process variables, 3200 alarms and others, OMV refinery attaches importance to proper functioning of the respective control instruments. The types of instruments used - pneumatic, analog and digital electronic, microprocessor-based electronic - are all maintained by specially skilled technicians. Work is scheduled and organized for shut-down periods and for operation periods. There exists an experience exchange group on instrumentation which meets annually for two days presenting a catalogue of questions/problems for discussions.

8. Maintenance of Process Analysis Instruments (H. Kloyber)

Due to the relatively large number of analyzers (625) to be controlled, the process analyzer department of OMV has been divided into four groups: pH group (conductivity, pH, oil in water); O_2 group (O_2, viscosity, CO, CO_2, CPA, sulfur, pour point, IR, H_2S, boiling point, opacity); gas detection group (hydrocarbons, H_2S, portable gas detectors); process chromatograph group (GC, moisture analyzer). These instruments must be controlled exactly according to their maintenance manuals. Calibration of these instruments is an important task and must follow standardized sampling and analysis methods.

9. Material Supply - Spare Parts Information Flow and Purchase (H. Kreisler)

Being a relatively large refinery and involved in exploration, pipeline transport, engineering and construction, OMV has decided on a centralized purchase department. The material catalogue comprises 60,000 items. The material administrator revises this catalogue and the warehouse stocks according to actual requirements from the refinery. A selective control

system has been developed which takes into account spare parts needed with higher frequency than others. Most of the materials are ordered from Austrian companies, USA and European companies with an average delivery time of 10 weeks, whereby four weeks are needed to comply with administrative regulations within the organization.

10. Material Management (G. Brantner, V. Klima)

Material management comprises the management of the warehouse, material handling and administration. An efficient material management can greatly reduce the shut-down time of a plant. Therefore security for material supply has high priority.

At OMV, 50% of the stored spare parts are permanently on stock, also for cases of unforeseen events. This long range planning requires capital cost. Efforts are therefore directed towards reducing these costs through improving warehouse administration. Storage of materials classified into material groups helps to locate material (sequential system) easily but requires a considerable amount of space. A new storage system was developed following the findings that 80% of stored parts are smaller than 950 x 200 x 350 mm. A computer-aided storage information system was created for locating parts. The new storage system needs only half the space of the old one. In addition, a computer programme is being developed to support material administration taking into account catalogue and technical information, purchasing, warehousing and accounting.

11. Plant Inspection in Petroleum Refineries (O.P. Hornasek)

Plant inspection in general addresses the following issues: corrosion, lifetime of equipment and scheduling of inspection, inspection methods, deterioration/failure of equipment and its prevention, detailed equipment inspection, on-stream inspection and special test methods.

Corrosion problems: In oil refineries mild steel is the material most commonly used and it suffers from corrosion at various degrees caused by a variety of sources. It is necessary to determine the nature and mechanism of corrosion so that suitable and economical methods may be applied for its prevention. Various remedial actions are discussed such as coating/linings, addition of inhibitors, cathodic protection, and some causes for corrosion such as chloride stress corrosion cracking, polythionic acid stress corrosion cracking, sulfide stress cracking, uniform corrosion, acid corrosion, caustic corrosion, high temperature corrosion, are described.

Schedules for equipment inspection: Government regulation (e.g. Austrian pressure vessel law) determines the frequency required for inspection, in general not less than every three years, and for hydrotesting every six years. Only under very special circumstances can this schedule be modified, if Government authorities agree. Inspection work to be carried out is listed and recorded at the beginning of the calendar year by the inspection department, covering the work for vessels, piping, safety valves and leaking glands. Examples for inspection schedules are demonstrated.

Inspection methods: This part describes the methods to be applied for the preparation and execution of inspection work. The following points have to be borne in mind: local Government regulations, construction code requirements, inspection service for corrosive and non-corrosive equipment. General inspection may be carried out through visual inspection, hammer testing, gagings, followed by very special inspection methods as required. To determine the remaining lifetime of a given piece of equipment requires considerable experience. The decision on whether or whether not to withdraw equipment from service may be guided by two considerations: (i) the minimal allowable wall thickness, and (ii) lack of justification for economically acceptable repair.

Cleaning for inspection: Various methods exist for this purpose ranging from water/steam washing, manual cleaning, sand blasting, brushing, reaming, chipping, to chemical and thermal methods.

Metal loss measurements and calculations: The parameters which govern the lifetime of equipment are: minimum allowable thickness, remaining corrosion allowance, corrosion rate, remaining life. An example for estimation of actual lifetime is presented. The various methods for corrosion rate measurements are described and their application explained.

In addition, the means for pressure testing are presented and procedures and safety considerations are explained. A very important work within inspection is welding, which requires very skilled personnel. Different types of welding necessary for inspection in petroleum refineries are listed and briefly described.

Deterioration/failure of equipment: The major cause for equipment failure is due to mechanical failure and corrosive attack. A review is presented on effects on various material and equipment, caused by mechanical stress and corrosion and oxidation. In addition, material exposed to a very special environment, such as high sub-critical temperature, overheating and others, may change its surface characteristics which may lead to dangerous conditions. Furthermore, the basic principles of cathodic protection are described and the different applications are outlined.

Lifetime of equipment: Very careful thought must be given to the judgement of lifetime to be expected for equipment. Premature retirement of equipment can waste money, while overdue utilization may cause failure with fatal consequences. Establishing the lifetime to be expected for a platforming heater is presented in detail as an example. Furthermore, an example for calculating remaining lifetime based on original and actual wall thickness is carried out (determination of remaining corrosion allowance and remaining life).

Detailed equipment inspection: Guidelines to be observed when a full inspection for any piece of equipment is called for, are laid down. Importance is attached to safety precaution and to the general safe limits of equipment. This is followed by a detailed description of a complete inspection, including nomenclature, design and retirement criteria, construction materials and repair and testing of the following equipment pieces: columns, pressure vessels, storage tanks, heat exchanger and cooling towers, process furnaces and boilers, pumps, turbines, compressors and machinery, instruments, piping and fittings, joints, bulk transmission lines, structures, fire proofing, insulations and foundations, and services.

On-stream inspection and special testing methods: The inspection of equipment in operation requires non-destructive testing methods (NDT-methods). However, many details cannot be detected while the unit is on-stream. The types and basic requirements of methods for on-stream inspection are described, which include visual inspection, ultrasonic, radiation tracer and infrared techniques as well as thermometric methods, radiation pyrometer method and acoustic emission methods. Examples are given on NDT acoustic inspection on pressure vessels and storage tanks and results are discussed.

12. Material Standards (Raaber, B. Wischin from TUV, Austria)

In general various types of materials are used as construction material for the equipment in a refinery depending on the type and the strength of stress to which it is exposed: for temperatures up to 400°C carbon and low alloy steel, for high temperatures chromium steel, austenitic steel, for high pressure in presence of hydrogen chromium steel, and others. The Austrian legislation on pressure vessels defines the standards under which quality systems certificates can be granted for certain products operating under pressure. In addition, inspection of these units must be done in the presence of TUV (Technical Inspection and Control Authority). Only with their certificate the tested unit can be put into operation.

13. Trouble Shooting (H. Miglitsch)

Trouble shooting and predictive maintenance are closely linked. Today's machinery, e.g., turbo-machinery is technically getting more and more sophisticated and better trouble shooting techniques have become essential. Some recommendations are given to avoid malfunctioning of turbo-compressors, turbines, reciprocating compressors and other rotating equipment, such as pumps, fans, gears units. For compressor and turbine units, permanent monitoring of the vibration is necessary since vibration is one of the most frequent causes of failure of such units.

14. Analytical Trouble Shooting (H. Huber)

Methods and techniques are presented for supporting decision making and prediction of critical situations. The four models of reasoning in daily routine work - namely to determine the reason for troubles, to choose the best measure, to recognize problems ahead of time, to split a complex situation into parts - can be optimized by rational techniques. Although the approach to decision making and problem solving as described is of general nature, its practical application to maintenance within a refinery will have an impact on the efficiency of such a refinery.

15. Recuperation of Flare Gas

Even at thorough, normal operation of refineries and petrochemical plants, combustible gases (flare gases and tail gases) are developed, which represent a considerable waste of energy. OMV has therefore developed an economic flare gas utilization process, whereby the flare gas is fed into the fuel gas system of the plant. Care must be taken to avoid air in the recuperation unit for well-known reasons. The operation of this plant is automatic to the greatest possible extent to keep the whole system economic. The plant presently installed at OMV has a nominal capacity of 5000 m^3/hour. The process has been patented.

16. Planning a Repair Shop (P. Kielhauser)

A detailed analysis shows that maintenance costs can be reduced by careful planning of repair shops for the refinery. The main questions to be answered are: What is the maintenance demand? How can this demand be met? Where should the repair shops be located? Will repair shops need extension? How to plan the internal organization? How to plan equipment storage? All planning steps have to undergo critical evaluation with a view to their impacts on economics.

17. Training of Maintenance Personnel (J. Schweng)

Maintenance work may be done by contractors or by own personnel. Most refineries follow a mixed system whereby services like cleaning, welding, etc. are done through contractor and long/short-term repair/ turnarounds by refinery personnel. Skilled personnel is usually provided through recruitment of specialists from other refineries or by on-the-job training of experienced workers from other industries. A very important source for skilled workers is established through an apprenticeship programme in Austria. Nearly 60,000 students start every year such an apprenticeship in various fields/trades, whereby the apprentice receives practical on-the-job training according to a well established and approved training schedule and theoretical training in a vocational school (dual system). After 3.5 years a certificate as a qualified worker is awarded. At ÖMV 60 new apprendiceships were started in 1983.

A large part of training of maintenance personnel is done during installation and start-up of new units when experienced workers from contractors, manufacturers, engineering companies work together with the own workshop personnel. This is the moment for acquiring know-how in trouble shooting and repair work.

New training methods such as audio-visual and video programmes are now available. In addition, interactive training systems and simulator systems can be applied which represent very powerful training techniques, especially for training in the operation and maintenance of highly sophisticated machinery and instrumentation.